EXHIBIT D

K010267

FEB 2 7 2001

510(k) Summary

Submitted by: Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street NW (#700)
Washington, DC 20036
202-261-1000

January 26, 2001

On behalf of Tokuyama America, Inc.
510(k) Submission: Tokuyama Palfique Estelite LV Clear

The product is a low viscous, light cured hybrid composite tooth shade resin material. It is intended for use in various dental procedures, including aesthetic restoration of surface enamel, post-restoration glazing of roughened surfaces of composite resin, restoration of deciduous teeth, fixture of loose teeth, reinforcement of occlusal surface, and basing before composite resin restoration.

The product incorporates the manufacturer's Sub-Micron Spherical SiO_2 - TiO_2 filler, which is also used in the manufacturer's Palfique Estelite LV (K002863), Palfique Estelite Paste (K980051), Palfiquelite Posterior (K913099), and Palfique (K897010). The product also incorporates well known monomers for filling material, including those used in the manufacturer's Palfique Estelite Paste (K980051), and Palfique Estelite LV (K002863).

Palfique Estelite LV Clear complies with the specifications of ISO 4749 and is substantially equivalent to Palfique Estelite Paste (Tokuyama - K980051), NTL-Flow (Bisco, Inc. - K974483), Flow Line (Heraus Kulzer, Inc. - K990756), Tetric Flow (Ivoclar North America, Inc.- K993783), and Aeliteflo (Bisco, Inc. K955292).

Palfique Estelite LV Clear may be used with Tokuyama's One-Up Bond F (K993917) or other brands of similar bonding agents. It is not intended for OTC use. It contains materials that are common in dental use and pose no health hazard when used according to directions.

The Use of the product is contra-indicated for patients who are hypersensitive to methacrylate or related monomers. It should not be allowed to come into contact with skin or eyes. Should the product come into contact with the eyes, it should be immediately and thoroughly rinsed out with water; a physician should be contacted at once. In the event of contact with skin and/or clothes, the skin or clothing should be cleaned immediately with an alcohol soaked cotton swab. It should not be used directly in a cavity having a pulpal exposure without first protecting exposed pulp with a lining and base material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2001

Tokuyama America, Incorporated
C/O Mr. Daniel J. Manelli
Attorney
Manelli, Denison & Selter, P.L.L.C.
2000 M Street, Suite 700
Washington, D.C. 20036

Re: K010267
Trade Name: Palfique Estelite LV Clear
Regulatory Class: II
Product Code: EBF
Dated: January 26, 2001
Received: January 29, 2001

Dear Mr. Manelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010267

Exhibit C

510(k) Number (if known): _____

Device Name: Tokuyama Palfique Estelite LV Clear

Indications For Use:

For use as a tooth shade resin material in dental procedures.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010267

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)